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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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077903,109 06/25/92 SCHLEGEL

C 010091-001

EXAMINER

FEIGEE, L

ART UNIT

PAPER NUMBER

1806

DATE MAILED:

11/18/92

BURNS, DOANE, SWICKER & MATHEIS  
GEORGE MASON BUILD  
WASHINGTON & PRINCE STS.  
P.O. BOX 1404  
ALEXANDRIA, VA 22313-1404

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been <sup>restricted</sup> examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 30 month(s), 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948.        |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____  |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-40 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☐ Claims \_\_\_\_\_ are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☒ Claims 1-40 are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Serial No. 903109

Art Unit 1806

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 and 10-18, drawn to a recombinantly produced protein and a vaccine comprising said protein, classified in Class 530,424 subclass 350,88.
- II. Claims 4-9, drawn to a vector and host, classified in Class 435, subclass 320.1, 252.3.
- III. Claims 19-26, drawn to a method of protection by administering a protein antigen, classified in Class 424, subclass 88.
- IV. Claims 27-29 and 38-40, drawn to compositions comprising antibodies, classified in Class 530, 424, subclass 388.3, 85.8.
- V. Claims 30-37, drawn to a method of treatment by administering an antibody, classified in Class 424, subclass 85.8.

The inventions are distinct, each from the other because of the following reasons:

Groups I, II and IV clearly differ in that they are structurally and functionally distinct and are made by different methods. The product of group I can be made through either purification or through recombinant DNA technology and may be used for immunoassays or purification of antibodies which are specific for the protein. The product of group II can be used to produce recombinant probes and finally the product of group IV can be used to isolate the product of group I and may be made by repeated immunization by the product of group I. Thus the products are clearly distinct and independent from each other and additionally differ in their classification scheme.

Inventions (I and IV) and (III and V) are related as product and process of use. The inventions can be shown to be

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distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case the antibodies of group IV may be used for treatment of the viral infection as well as the antigen of group I and the disease can be treated two different ways ie. either by active immunization or by passive immunization.

The methods of groups III and V are patentably distinct in that the steps and the reagents used to carry out the two methods are distinct each from the other. Because of the difference in reagents, the mechanism of action of the methods is different, eg. the method of group III is primarily an active immunization protocol, while the method of group V is essentially a passive immunization protocol. The results obtained by the two methods will vary greatly.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, and because the searches for the individual Groups are not coextensive, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Dubois, on 11/5/92, to request an oral election to the above restriction requirement, but did not result in an election being made as applicant requested that a written restriction be mailed out.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must

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be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

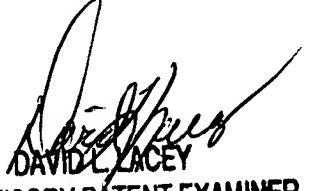
Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. (37 C.F.R. 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lila Feisee whose telephone number is (703) 308-2731.

10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 15 via the PTO FAX Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 FAX Center number is (703) 308-4227. The hours of operation of the Center are 8:45 am - 4:45 pm, Monday - Friday.

20 Feisee/lf   
November 13, 1992

  
DAVID L. LACEY  
SUPERVISORY PATENT EXAMINER  
GROUP 180

11/16/92 